sons. Utilization and hospitalization outcomes were collected monthly throughout respective seasons. **RESULTS:** A total of 13,310 infants were enrolled (309 CAA, 1816 MD, 11185 SD). There were statistically significant group differences (p<0.05) in: enrolment and gestational age, birth and enrolment weight, proportions of: Caucasians, daycare attendance, smoking exposure, siblings, multiple birth, household crowding, and atopy. Compliance, calculated by inter-dose intervals, was similar across the groups - overall rate 73.2%. CAA infants had a RIH rate of 12.9%; MD (9.9%); SD (5.9%) with significantly increased hazard of hospitalization compared to MD (HR = 1.47, 95%CI: 1.04-2.10, p = 0.030) and SD (HR = 1.92, 95%CI: 1.39-2.67, p < 0.0005). 40/309 CAA infants were hospitalized for RI, 32 were tested for RSV; 4 were positive (RSVH rate: 1.61% versus 2.06% (MD), 1.47% (SD). By Cox proportional hazard analysis, CAA did not increase hazard of first RSVH compared to MD or SD infants ($\chi^2 = 0.79$, df = 2, p = 0.67). After risk factor adjustment for daycare attendance, siblings, smoking exposure and crowding, the model was significant ($\chi^2 = 66.1$, df = 10, p < 0.0005); however, individual groups as risk factors remained insignificant (p = 0.73). **CONCLUSIONS:** This is the largest report of CAA infants who have received palivizumab world-wide. Despite differences in risk factors, the groups appear to have similar hazards in terms of RSVH.

PRS6

SYSTEMATIC REVIEW OF COLISTIMETHATE SODIUM DRY POWDER AND TOBRAMYCIN DRY POWDER ANTIBIOTICS FOR PSEUDOMONAS AERUGINOSA LUNG INFECTION IN CYSTIC FIBROSIS

Harnan SE[1], Uttley L[1], Cantrell A[2], Taylor CJ[3], Walshaw M[4], Brownlee K[5], Tappenden P[2]
[1]*The University of Sheffield, Sheffield, UK,* [2]*University of Sheffield, Sheffield, UK,* [3]*Sheffield Children's NHS Foundation Trust, Sheffield, UK,* [4]*Liverpool Heart and Chest Hospital NHS Foundation Trust, Liverpool, UK,* [5]*Leeds Children's Hospital, Leeds General Infirmary, Leeds, UK*

OBJECTIVES: To evaluate the clinical effectiveness of colistimethate sodium dry powder for inhalation (DPI) and tobramycin DPI for the treatment of Pseudomonas aeruginosa lung infection in cystic fibrosis. **METHODS:** Electronic bibliographic databases were searched in May 2012 (MEDLINE, MEDLINE in-Process, EMBASE, Cochrane Library databases, CINAHL, Web of Science and Conference Proceedings Citation Index, BIOSIS Previews). Randomised controlled trials were selected for inclusion in the review if they included at least one of the interventions of interest and reported at least one of the following outcomes: rate and extent of microbial response (e.g. sputum density of Pseudomonas aeruginosa); lung function (e.g. forced expiratory volume in one second % predicted (FEV1%); respiratory symptoms; frequency and severity of acute exacerbations; health-related quality of life; and adverse events of treatment (including rate of resistance to antibiotic treatment). **RESULTS:** Three poor to moderate trials were included in the review. Both dry powder formulations were reported to be non-inferior to nebulised tobramycin in terms of clinically relevant changes in FEV1%. However, follow up may not be long enough to detect slowing of the rate of decline in respiratory function and exacerbation rates were not always reported. It was not possible to draw any firm conclusions as to the relative efficacy of the treatments. **CONCLUSIONS:** Whilst both dry powder drugs were reported to be non-inferior to nebulised tobramycin, some results should be interpreted with caution due to the means by which they were analysed, the length of follow up, and concerns about the ability of FEV1% to accurately represent changes in lung health. The clinical trials should have considered FEV1% alongside other clinically relevant outcomes, such as acute exacerbations. This study illustrates the difficulty in assessing new technologies where the evidence base is poor.

PRS7

ASSESSING NON-INFERIORITY OF ACLIDINIUM BROMIDE 400 µG BID VERSUS TIOTROPIUM 18 µG AND 5 µG QD IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) BY MEANS OF A NETWORK META-ANALYSIS

Karabis A[1], Lindner L[2], Prior M[3]
[1]*Mapi, Houten, The Netherlands,* [2]*Almirall UK, Uxbridge, UK,* [3]*Almirall S.A., Barcelona, Spain*

OBJECTIVES: To assess non-inferiority (NI) of aclidinium bromide 400 µg BID (AB400), to tiotropium bromide 18 µg (TIO18) and 5 µg (TIO5) QD in patients with COPD. **METHODS:** A systematic literature search identified 21 RCTs: TIO18 (16 trials), TIO5 (3 trials) and AB400 (2 trials). All trials were analysed using a Bayesian network meta-analysis (NMA) and relative treatment effects between all regimens were obtained for change from baseline (CFB) in FEV_1 trough, SGRQ total score, and TDI focal score, at 24 weeks. The posterior distributions of the relative treatment effects were used to estimate the probability of non-inferiority, based on the NI margins. Two approaches used for margin selection (a) NI_{MCID}: 50% of the Minimum Clinically Important Difference (MCID) (b) NI_{NMA}: 50% of the difference between TIO18 and placebo (PLA), based on the NMA results. AB400 was considered non-inferior if it could maintain at least 50% of this difference with a probability >99%. **RESULTS:** For FEV_1 the MCID is 100mL, while the CFB for TIO18 vs. PLA is 104.1mL giving NI_{MCID}=50mL, NI_{NMA}=52.05mL. AB400 is shown to be non-inferior to TIO5 and TIO18, for both margins. For SGRQ, a change of 4 points is the MCID and CFB for TIO18 vs. PLA is 2.65, thus NI_{MCID} = 2 and NI_{NMA}= 1.325. AB400 was shown to be non-inferior to TIO5 and TIO18 for both margins. A difference of 1 unit is the MCID for TDI, while the CFB for TIO18 vs. PLA is 0.90 unit, giving NI_{MCID} = 0.5, NI_{NMA} = 0.45. For these margins, the probability of aclidinium been non-inferior is 97% for the NI_{MCID}, and 96% for the NI_{NMA}. **CONCLUSIONS:** This analysis suggests that treatment with AB400 in COPD is non-inferior to TIO18 and TIO5 with respect to lung function, health status, and to breathlessness with a probability >95%.

PRS8

EFFECTIVENESS OF MONTELUKAST ON ASTHMA CONTROL IN INFANTS: METHODOLOGY OF A CLAIMS DATA STUDY

Belhassen M[1], Tamberou C[1], Laigle V[2], Souchet T[2], Chanut-Vogel C[2], Lamezec L[2], De Blic J[3], Brouard J[4], Fauroux B[5], de Pouvourville G[6], Laforest L[1], Van Ganse E[1]
[1]*University of Lyon, Lyon, France,* [2]*Laboratoires MSD France, Courbevoie, France,* [3]*Necker University Hospital, Paris, France,* [4]*University Hospital Caen, Caen, France,* [5]*Trousseau University Hospital, Paris, France,* [6]*ESSEC, Cergy-Pontoise, France*

OBJECTIVES: Montelukast 4mg (MTL-4) is a recent add-on therapy for young asthmatic children. French regulators have requested real-world evidence on effectiveness of MTL-4 in infants (6-24 months), compared to inhaled corticosteroid (ICS) therapy. National claims data (SNIIR-AM) are now available to public investigators. SNIIR-AM records exhaustive medical resource utilization of the French population, i.e. 65.4 millions. Due to the limited population of infants exposed to MTL-4 from 2010 (i.e. 78 000 children 6-24 months old), SNIIR-AM represents a good tool to investigate its effectiveness. We first tested the feasibility of such a study in a pilot phase conducted on a 1/97th representative sample of the full data set (EGB: Representative Sample of Beneficiaries), to validate identification and evaluation criteria, and to identify potential pitfalls in the methods or insufficient statistical power for groups comparison, in order to take them into account in the finalized version of the protocol. We present hereafter the main conclusions of the pilot project. **METHODS:** We preselected infants receiving ≥ 2 consecutive dispensations of any respiratory drugs (R03 ATC classification) and presenting an initial exacerbation within 6 months following the first dispensing. Asthma exacerbation was identified by asthma-related hospitalizations, dispensing of oral corticosteroids, addition of short-acting beta agonist to existing respiratory therapy, switch to an ICS therapy with higher dosage, or switch to nebulized CS. **RESULTS:** Our sample included 1,149 infants (mean age 13 months, 64% boys). Among them, 51 and 768 were assigned to Montelukast and ICS groups, respectively. Infants with a exacerbation during the 6 months post inclusion were 78.8% and 78.4% in each group, respectively (51% and 62% for oral costicosteroids only). **CONCLUSIONS:** The results of this pilot study support the feasibility of our SNIIR-AM project, regarding inclusion criteria and identification of outcomes. These data allowed us to finalize the SNIIR-AM study protocol that is ongoing.

PRS9

CURRENT CHARACTERISTICS, TREATMENT AND HEALTH CARE CONSUMPTION OF PATIENTS WITH ASTHMA OR COPD IN THE NETHERLANDS

Overbeek JA[1], Driessen MT[2], Penning-van Beest FJA[1], Rutten-van Mölken M[3], Lammers JWJ[4], Herings RMC[1]
[1]*PHARMO Institute for Drug Outcomes Research, Utrecht, The Netherlands,* [2]*GlaxoSmithKline, Zeist, The Netherlands,* [3]*Institute for Medical Technology Assessment, Rotterdam, The Netherlands,* [4]*University Medical Center Utrecht, Utrecht, The Netherlands*

OBJECTIVES: To investigate the characteristics, medication persistence and health care consumption of asthma and COPD patients in The Netherlands in 2011. **METHODS:** Data were obtained from the PHARMO Database Network, including outpatient drug dispensings, hospitalization records and information from general practitioners (GP). From the GP-database, patients with a recorded ICPC-code for asthma or COPD (period 2001-2010) were selected and included if they were continuously registered in 2010-2011 and had ≥1 respiratory dispensing in 2010. Persistence with any respiratory medication was determined among new patients and defined as the number of days of uninterrupted use. **RESULTS:** The study included 6037 asthma and 4489 COPD patients. In 2011, most asthma patients were most often categorized into GINA I (n=1727), female (60%) and had a mean age of 45 (SD±18) years. COPD patients were classified as GOLD II (n = 1485), male (54%) and had a mean age of 67 (SD±11) years. On January 1, 2011, most common used respiratory treatment among asthma patients was fixed-dose combination of LABA+ICS (FDC) (25%), whereas COPD patients mostly either used FDC (14%), LAMA (14%) or both (15%). 30% Of asthma and 16% of COPD patients did not use respiratory medication. Among new asthma patients, after six and twelve months, 22% and 10% of patients were persistent with respiratory medication. These proportions were 42% and 30% for COPD. Most common selected co-morbidities among both groups were hypertension, hypercholesterolemia, and depression. In 2011, asthma patients consulted their GP on average 5.3 times and COPD patients 7.7 times. On average, asthma patients were 0.4 days hospitalized and COPD patients 1.2 days. Cost calculations for health care consumption are available in November. **CONCLUSIONS:** This study provides an overview of the characteristics and health care consumption of asthma and COPD patients in The Netherlands, and emphasizes the need for more research regarding persistence among these patients.

PRS10

ESTIMATION OF THE NUMBER OF CASES OF NOSOCOMIAL PNEUMONIA IN ADULTS CAUSED BY GRAM-POSITIVE BACTERIA IN PUBLIC HOSPITALS IN MEXICO

Gryzbowski E[1], Peniche-Otero G[1], Herrera-Rojas J[1], Bolaños-Cornejo D[1], Huicochea-Bartelt JL[2], Muciño-Ortega E[2]
[1]*Customized Premium Products S.A. de C.V., Mexico City, Mexico,* [2]*Pfizer S.A. de C.V., Ciudad de México, Mexico*

OBJECTIVES: To estimate the number of cases of nosocomial pneumonia (NP) in adults caused by Gram-positive bacteria (GPB) in public hospitals in Mexico. **METHODS:** To estimate the number of hospital discharges for each public institution in ≥ 18 years, databases from the National Health Information System (SINAIS) were consulted. We apply the nosocomial infection (NI) rate (5.97 cases per 100 discharges) issued by Instituto Mexicano del Seguro Social (IMSS) during the period 2011-2012. Through a systematic literature review and critical reading of studies developed in the Mexican setting (using the Critical Appraisal Skills Programme guidelines) we assessed the type of infection and determined the proportion of cases in which microbiological culture was obtained, as well as the proportion giving positive isolates; subsequently, etiologic agent was disaggregated according to their Gram staining characteristics. **RESULTS:** In the year 2011 there were 5,517,139 discharges from public hospitals, applying a rate of 5.97 NI cases/100 discharges, resulted in 329,373 NI cases (16.9% under 18 years and 83.1% in adults). The NP represented 33.2% of NI (90,882 cases), of these, only in 63% of cases a microbiological culture was obtained (57,256) and pathogens were isolated in 87.0% of microbiological cultures (49,813), among these, GPB we identified in 30.4% . According to our estimates the number of cases of adult NP caused by GPB is 15,135 and the pathogens reported were *Staphylococcus aureus* (74.3%), Streptococcus pneumoniae (15.6%), Enterococcus spp. (6.3%) and others (3.8%). **CONCLUSIONS:** In